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Docket No.: 60710-00002USC1

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Charles F. Brunicardi

Application No.: 10/656450

Confirmation No.: 8472

Filed: September 5, 2003

Art Unit: 1632

For:

PROMOTER DRIVEN TISSUE SPECIFIC CYTOTOXIC AGENTS AND METHODS OF

Examiner: Not Yet Assigned

USE

<u>INFORMATION DISCLOSURE STATEMENT (IDS)</u>

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached substitute for form 1449A/B/PTO. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The attached substitute lists the same references as were provided with an Information Disclosure Statement (IDS) for a related family member -- continuation application 10/948,872. Also, all references except thirteen references (i.e., CZ1, CA2, CB2, CB2, CC2, CD2, CE2, CF2, CG2, CH2, CA3, CB3 and CC3) were listed with an IDS, or cited by the Examiner, in the prosecution of parent application 09/686,631 (now U.S. Patent No. 6,716,824). Of the remaining thirteen references, the first ten references (i.e., CZ1, CA2, CB2, CB2, CC2, CD2, CE2, CF2, CG2, CH2) were previously provided in an IDS submitted December 14, 2003 for this application. The remaining three references (i.e., CA3, CB3 and CC3, which are provided with this IDS) are:

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Application No.: 10/656450 Docket No.: 60710-00002USC1

CA3	WANG et al., "Specific Gene Expression and Therapy for Pancreatic Cancer							
	Using the Cytosine Deaminase Gene Directed by the Rat Insulin Promoter", J							
	of GASTROINTESTINAL SURGERY, 2004, Vol. 8 No. 1: 98-108.							
CB3	TIRONE et al., "Insulinoma-Induced Hypoglycemic Death in Mice is							
	Prevented with Beta Cell-Specific Gene Therapy", ANNALS OF SURGERY,							
	May 2001, Vol. 233, No. 5: 603-611							
CC3	TIRONE et al., "Cell-specific Cytotoxicity of Human Pancreatic							
	Adenocarcinoma Cells Using Rat Insulin Promoter Thymidine Kinase-							
	directed Gene Therapy", WORLD J. OF SURGERY, 2004, 28: 826-833.							

This IDS is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

In accordance with 37 CFR 1.97(g), the filing of this IDS shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this IDS shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the IDS is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 10-0447, under Order No. 60710-00002USC1.

Dated: May 9, 2005

Respectfully submitted,

Mark J. Gatschet

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By Mark J. Hatschet

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Attorneys For Applicant

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First Named Inventor	Charles F. Brunicardi
Art Unit	1632
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Attorney Docket Number	60710-00002USC1

	EN	CLOSURES (Check all that app	ply)		
Fee Transmittal For	m	Drawing(s)	After Allowance Communication to TC		
Fee Attached		Licensing-related Papers	Appeal Communication to Board of Appeals and Interferences		
Amendment/Reply		Petition	Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)		
After Final		Petition to Convert to a Provisional Application	Proprietary Information		
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Complete if Known Substitute for form 1449A/B/PTO Application Number 10/656450 INFORMATION DISCLOSURE Filing Date September 5, 2003 STATEMENT BY APPLICANT First Named Inventor Charles F. Brunicardi Art Unit 1632 (Use as many sheets as necessary) Examiner Name Not Yet Assigned Sheet 1 Attorney Docket Number 60710-00002USC1

	U.S. PATENT DOCUMENTS						
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where		
Initials*	No.1	Number-Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear		
	AA**	US-5,997,859-A1	12-07-1999	Barber et al.	- i		
	AB**	US-6,066,624-A1	05-23-2000	Woo et al.			
	AC**	US-6,241,982B1-A1	06-05-2001	Barber et al.			
	AD**	US-6,217,860B1-A1	04-17-2001	Woo et al.			
	AE**	US-5,674,703-A1	10-07-1997	Woo et al.			
		US-5,631,236-A1	05-20-1997	Woo et al.			
	AG**	US-5,811,266-A1	09-22-1998	Newgard			
	AH**	US-5,952,221-A1	09-14-1999	Kurtzman et al.			
	AI**	US-5,723,333-A1	03-03-1998	Levine et al.			
	AJ**	US-5,885,971-A1	03-23-1999	German et al.			
	AK**	US-5,880,261-A1	03-09-1999	Waeber et al.			
	AL**	US-5,863,794-A1	01-26-1999	Strayer			
	AM*	US-5,837,693-A1	11-17-1998	German et al.			
	AN**	US-5,837,283-A1	11-17-1998	McDonald et al.			
	AO**	US-5,792,656-A1	08-11-1998	Newgard			
	AP**	US-5,747,325-A1	05-05-1998	Newgard			
		US-5,858,973-A1	01-12-1999	Habener et al.			
	AR**	US-5,728,379-A1	03-17-1998	Martuza et al.			

		FOREI	GN PATENT	DOCUMENTS		_
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	BA**	WO-WO 95/05835-A1	03-02-1995			\vdash

*EXAMINER: initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filling date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.usplo.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). * For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	ner Cite No.1 Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publi and/or country where published.						
	CA**	DIMAIO et al., "Directed enzyme pro-drug gene therapy for pancreatic cancer <i>in vivo</i> ", SURGERY, Vol. 116, No. 2, 1994, pp. 205-213.					
	CB**	EASTHAM et al., "Prostate Cancer Gene Therapy: Herpes Simplex Virus Thymidine Kinase Gene Transduction Followed by Ganciclovir in Mouse and Human Prostate Cancer Models", HUMAN GENE THERAPY, 1996, 7:515-523.					
	CC**	FRAZIER, "Gene Expression in Pancreatic Adenocarcinoma", ANNALS NEW YORK ACADEMY OF SCIENCES, 1999, 880:1-4.					
	CD**	HAMAGUCHI et al., "NIT-1, A Pancreatic β-Cell Line Established from a Transgenic NOD/Lt Mouse", DIABETES, 1991, 40:842-849.					

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Sub	ostitute for form 1449A/B/PT	o		Complete if Known		
				Application Number	10/656450	
11	NFORMATION	1 DI	SCLOSURE	Filing Date	September 5, 2003	
S	TATEMENT E	3Y /	APPLICANT	First Named Inventor	Charles F. Brunicardi	
				Art Unit	1632	
	(Use as many sh	eets as	s necessary)	Examiner Name	Not Yet Assigned	
Sheet	2	of	4	Attorney Docket Number	60710-00002USC1	

	CE**	HARDY et al., "Construction of Adenovirus Vectors through Cre-Lox Recombination", JOURNAL OF VIROLOGY, Vol. 71, No. 3, 1997, pp. 1842-1849.	
	CF**	KATABI et al., "Hexokinase Type II: A Novel Tumor-Specific Promoter for Gene-Targeted	
		Therapy Differentially Expressed and Regulated in Human Cancer Cells", HUMAN GENE THERAPY, 1999, 10:155-164.	
<u> </u>	CG**	KANEKO et al., "Adenovirus-mediated Gene Therapy of Hepatocellular Carcinoma Using	
		Cancer-specific Gene Expression", CANCER RESEARCH, 1995, 55:5283-5287.	
1	CH**	KIJIMA et al., "Application of the Cre Recombinase/loxP System Further Enhances Antitumor	
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	CI**	KUMAR et al., "Subtype-Selective Expression of the Five Somatostatin Receptors (hSSTR1-5)	
		in Human Pancreatic Islet Cells: A Quantitative Double-Label Immunohistochemical Analysis", DIABETES 1999, 48:77-85.	
	CJ**	LIEBER et al., "Establishment of a Continuous Tumor-Cell Line (PANC-1) from a Human	
		Carcinoma of the Exocrine Pancreas", INT. J CANCER, 1975, 15:741-747.	
	CK**	NAYA et al., "Diabetes, defective pancreatic morphogenesis, and abnormal entercendocrine	
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		CANCER RESEARCH, 194, 54:5258-5261.	
	CM**	ROBERTSON, et al., "Use of tissue-specific promoter for targeted expression of the herpes	
1		simplex virus thymidine kinase gene in cervical carcinoma cells", CANCER GENE THERAPY,	
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†	CN**	SANDER et al., "The β cell transcription factors and development of the pancreas", J. MOL	
		MED., 1997, 75(5):327-340 (14 pp).	
	CO**	SCHWARTZ et al., "An orthotopic <i>in vivo</i> model of human pancreatic cancer", SURGERY VOL. 126, No. 3, 1999, pp. 562-567.	
[CP**	SIDERS et al., "Melanoma-specific cytotoxicity induced by a tyrosinase promoter-	
		enhancer/herpes simplex virus thymidine kinase adenovirus", CANCER GENE THERAPY Vol. 5, No. 5, 1998, pp. 181-291.	
	CQ**	TIRONE et al., "Alterations in Insulin Secretion in the Somatostatin Subtype Receptor 5	
		Knockout Mouse Using the Isolated Perfused Mouse Pancreas Model", SURGICAL FORUM.	
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		loxP System", BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, 1998,	
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	CW**	MOLDOVAN et al., "Cloning of the Mouse SSTR5 Gene", JOURNAL OF SURGICAL	
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Examiner	Date		
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Sheet	3	of	4	Attorney Docket Number	60710-00002USC1	

	CX**	REN et al., "Activation of Human Somatostatin Receptor Type 2 Causes Inhibition of Cell	
1		Growth in Transfected HEK293 but not in Transfected CHO Cells", JOURNAL OF SURGICAL RESEARCH, 1997, 71:13-18.	
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		isolated Perfused Human Pancreas", PANCREAS, Vol. 9, No. 2, pp. 172-178.	
	CZ**	AHLGREN et al., "Beta-cell-specific inactivation of the mouse lpf1/Pdx1 gene results in loss of	
	_	the β-cell phenotype and maturity onset diabetes", GENES & DEVELOPMENT, 1998,	
		12:1763-1768.	
	CA1**	AL-HENDY et al., "Applying the Herpes Simplex Virus Thymidine Kinase/Ganciclovir Approach	
1		to Ovarian Cancer: An Effective in vitro Drug-Sensitization System", GYNECOLOGIC AND	
		OBSTETRIC INVESTIGATION, 1997, 43:268-275.	
	CB1**	BONNEKOH et al., "Inhibition of Melanoma Growth by Adenoviral Mediated HSV Thymidine	
		Kinase Gene Transfer in vivo", THE JOURNAL OF INVESTIGATIVE DERMATOLOGY, 1995,	
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		the Expression of CRE Recombinase in a Tissue-Specific Manner", INTERNATIONAL	
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	J1 1	Construct", Association of Academic Surgery-Abstracts, 33rd Annual Meeting, Philadelphia,	
		PA, Nov. 18-20, 1999, pp. 287-288.	
	CG1**	SMYTH-TEMPLETON et al., "Improved DNA: liposome complexes for increased systemic	
		delivery and gene expression", NATURE BIOTECHNOLOGY, 1997, 15:647-652.	
(CH1**	ST-ONGE et al., "Pancreas development and diabetes", CURRENT OPINION IN GENETICS	
		DEVELOPMENT 1999, 9:295-300.	
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		Subtypes: An in vitro Study of Pancreatic Islets from Somatostatin Receptor 2 Knockout Mice",	
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 '	CJ1**	TANAKA et al., "Adenovirus-Mediated Gene Therapy of Gastric Carcinoma Using Cancer-	
		Specific Gene Expression in vivo", BIOCHEMICAL AND BIOPHYSICAL RESEARCH	
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	CK1**	TONG et al., "In vivo Gene Therapy of Ovarian Cancer by Adenovirus-Mediated Thymidine	
		Kinase Gene Transduction and Ganciclovir Administration", GYNECOLOGIC ONCOLOGY, 1996, 61:175-179.	
 ,	CL1**	VANDIER et al., "Selective Killing of Glioma Cell Lines Using an Astrocyte-specific Expression	
	JL 1	of the Herpes Simplex Virus-Thymidine Kinase Gene", CANCER RESEARCH, 1998,	
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-		Ovarian Cancer Cell Lines Followed by Exposure to Ganciclovir", ANTICANCER	
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		2000, SURGICAL ONCOLOGY, Vol. 9, Elsevier, pp. 181-191.	
]	CO1**	MELLOUL et al., "Regulation of insulin gene transcription", 2002, DIABETOLOGIA, Springer-	
		Vertag, pp. 309-326.	
]	CP1**	RAY et al., "Beta Cell-Specific Ablation of Target Gene Using Cre-loxP System in Transgenic	
L		Mice", 1999, JOURNAL OF SURGICAL RESEARCH, Vol. 84, pp. 199-203.	
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Sheet	4	of	4	Attorney Docket Number	60710-00002USC1	

	LEDLEY, "Clinical Considerations in the Design of Protocols for Somatic Gene Therapy", 1991, HUMAN GENE THERAPY 2:77-83.	
CR1**	ECK et al., "Gene-Based Therapy", 1990:77-100.	
CS1**	MILLER et al., "Targeted vectors for gene therapy", 1995, FASEB J., 9:190-199.	
CT1**	DEONARAIN, "Ligand-targeted receptor-mediated vectors for gene delivery", 1998, Ecp. Opin. Ther. Patents 8(1):53-69.	
	VERMA et al., "Gene therapy-promises, problems and prospects", 1997, NATURE, Vol. 389:239-242.	
CV1**	CRYSTAL, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success", 1995, SCIENCE, Vol. 270:404-410.	
CW1*	ROMANO et al., "Gene Transfer Technology in Therapy: Current Applications and Future Goals", 1999, Stem Cells 17:191-202.	
CX1**	WELSH et al., "Stimulation of pancreatic islet beta-cell replication by oncogenes", 1988, Proc. Natl. Acad. Sci., Vol. 85:116-120.	
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CZ1**	Administration in Patients with Recurrent Malignant Brain Tumors", MOLECULAR THERAPY, 2000, Vol. 1, No. 2, pp. 195-203.	
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CC2**	TIRONE et al., "Cell-Specific Cytotoxicity of Human Pancreatic Adenocarcinoma Cells using Rat Insulin Promoter Thymidine Kinase Directd Gene Therapy", Michael E. DeBakey Dept. of Surgery, Dept. of Molecular and Cellular Biology and Center for Cell and Gene Therapy, Baylor College of Medicine, Houston, TX, pp. 2-32.	
CD2**	YAZAWA et al., "Current Progress in Suicide Gene Therapy for Cancer", WORLD JOURNAL OF SURGERY", 26, PP. 783-789, 2002.	
CE2**	KOURAKLIS, "Progress in cancer gene therapy", ACTA ONCOL., 1999:38(6):675-83.	
CF2**		
CG2**		
CH2**	SHALEV et al., "Suicide gene therapy for prostate cancer using a replication-deficient adenovirus containing the herpesvirus thymidine kinase gene", WORLD J UROL. 2000 18:125-129.	
CA3	WANG et al., "Specific Gene Expression and Therapy for Pancreatic Cancer Using the Cytosine Deaminase Gene Directed by the Rat Insulin Promoter", J of GASTROINTESTINAL SURGERY, 2004, Vol. 8 No. 1:98-108.	
CB3	TIRONE et al., "Insulinoma-Induced Hypoglycemic Death in Mice is Prevented with Beta Cell-Specific Gene Therapy", ANNALS OF SURGERY, Vol. 233, No. 5, May 2001;603-611	
CC3	TIRONE et al., "Cell-specific Cytotoxicity of Human Pancreatic Adenocarcinoma Cells Using Rat Insulin Promoter Thymidine Kinase-directed Gene Therapy", WORLD J. OF SURGERY, 2004, 28, 826-833.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double

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Application No. (if known): 10/656450

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IDS (Substitute for Form 1449A/B/PTO) (4 pages w/ 3 New References)

Reference CA3 (11 pages) Reference CB3 (9 pages) Reference CC3 (8 pages)

Information Disclosure Statement (2 pages)

Transmittal Form (1 page)

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